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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,206	11/12/1999	RIYI SHI	7024-427-PUR	9018

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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/438,206	SHI ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become* ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-30,38-40,43 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30, 38-40, and 43-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2-27-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendments filed February 27, 2004 have been entered.

Claims 22-30, 38-40, and 43-44 are pending.

The outstanding rejection under 35 USC 112 has been withdrawn in view of the amendments filed February 27, 2004.

The outstanding rejection under 35 USC 102(b) is withdrawn in view of the amendments filed February 27, 2004. The claims are now directed to a method of treating spinal cord injury employing composition not containing benzyl alcohol. The specific exclusion of benzyl alcohol in the claims will obviate the cited prior art.

The outstanding rejection under 35 USC 103(a) over Duck in view of Potter is withdrawn in view of the amendments filed February 27, 2004.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-29, 38-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/132,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '542 patent recites the method of treating a mammalian nerve tissue injuries with a biofusion materials. '542 teaches that the preferred biofusion material as polyethylene glycol (See claims 3 and 4 particularly) and the nerve tissue injuries can be spinal cord injuries (See claim 17). One of ordinary skill in the art would have been motivated to employ polyethylene glycol (the preferred agent in '542) in a method to treat spinal cord injuries (the specific recited nerve tissue injury in '542). Employing any preferred biofusion agents, such as polyethylene glycol, would have been reasonably expected to be useful in treating any nerve tissue injuries, including spinal cord injuries.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's arguments averring the conflicting application not being patented and therefore, requesting withdrawal of the double patenting rejection have been considered, but are not found persuasive. Examiner notes that the rejection is actually a provisional double patenting. Therefore, by definition, the conflicting application has not been patented yet.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-30, 38-40, and 43-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "wherein the composition does not contain benzyl alcohol" recited in the claims is not supported by the originally filed specification and claims. Because of the recited limitation, the scope of the claims has been changed. Such change of the scope of the claims is not supported by the originally filed specification and claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 24-30, 38-40 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian (US Patent 5,382,584) in view of Potter et al. (Clin Invest Med, 19(4), Suppl.: S80, #533). Potter is reference of record.

Balasubramanian teaches a method of employing piperazinyl phenylacetamide compounds useful as treatment for spinal cord injuries broadly (see col. 4, line 2). Balasubramanian also teaches one of the routes to administer the piperazinyl phenylacetamide compounds as intrathecal (See col. 5, line 6). Balasubramanian also teaches when administering the piperazinyl phenylacetamide compounds parenterally, such compounds will be formulated into solution or suspension with suitable solvent such as polyethylene glycol 200-1500 (See col. 6, lines 17-27).

Balasubramanian does not expressly teach 4-aminopyridine, a potassium channel blocker, can be combined with method of treating spinal cord injury such as crushed spinal cord injury. Balasubramanian does not expressly teach specifically administering the piperazinyl phenylacetamide compounds with polyethylene glycol 200-1500 intrathecally.

Potter et al. teaches the use of 4-aminopyridine to treat spinal cord injury (See #533).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 4-aminopyridine with the piperazinyl phenylacetamide compounds of Balasubramanian to treat spinal cord injuries such as crushed spinal cord injury. It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the piperazinyl phenylacetamide with polyethylene glycol 200-1500 intrathecally in a method to treat spinal cord injuries.

One of ordinary skill in the art would have been motivated to employ 4-aminopyridine with the piperazinyl phenylacetamide compounds of Balasubramanian to treat spinal cord injuries such as crushed spinal cord injury. 4-aminopyridine is known to be useful as treatment for spinal cord injury. The polyethylene glycol containing formulation of Balasubramanian is also known to treat spinal cord injury. Employing them concomitantly for treating the very same condition, spinal cord injuries, would be obvious (*In re Kerkhoven* 205 USPQ 1069).

One of ordinary skill in the art would have been motivated to administer the piperazinyl phenylacetamide with polyethylene glycol 200-1500 intrathecally (Note: a

polyethylene glycol containing composition) in a method to treat spinal cord injuries such as crushed spinal cord injury. Since the piperazinyl phenylacetamide compounds of Balasubramanian are known to be useful to treat spinal cord injury. Administering such compounds intrathecally, in solution form with polyethylene glycol 200-1500, to treat spinal cord injury would have been reasonably expected to be effective. It is known that polyethylene glycol is the exemplified solvent useful to dissolve the piperazinyl phenylacetamide compounds of Balasubramanian. Employing polyethylene glycol as the solvent would be considered as selecting from obvious alternatives. The skilled of artisan would possess all conventional administration method of the active compounds such as oral administration. The selection of one or another route of administration would be seen as a simple selection from among obvious alternatives.

Response to arguments

Applicant's rebuttal arguments filed February 27, 2004 averring the cited prior art's failure to teach all limitations of the claims, especially the resulted neuronal effect have been considered, but are not found persuasive. The cited prior art teaches the employment of polyethylene glycol containing composition to treat spinal cord injury. The resulted neuronal recovery must be present since the cited prior art teaches the employment of the herein claimed compound to treat spinal cord injury.

Applicant's arguments averring the prior art's recognition of polyethylene glycol as ineffective in treating neuronal injury by citing Balasubramanian, col. 4, lines 40-46, and the cited prior art's failure to suggest the herein claimed invention have been

considered, but are not found persuasive. Balasubramanian, col. 4, lines 40-46 does not expressly teach polyethylene glycol as the vehicle employed in the experiment. Moreover, Balasubramanian, col. 4, lines 40-46 merely teaches the vehicle is not as effective in reduce infraction as compared to the compounds of Balasubramanian, it does not teach the vehicle is not effective at all. Furthermore, Balasubramanian, col. 4, lines 40-46 teaches the effect of vehicle in reducing the infraction. It does not teach that the vehicle is ineffective in neuronal activity recovery. Examiner notes that the instant claims encompasses a method of treating spinal cord injury by employing any composition containing polyethylene glycol or C_1-C_{10} polyalkylene glycol. In the instant case, the method of Balasubramanian suggests the use of polyethylene glycol, although as a vehicle, with the compounds of Balasubramanian to treat spinal cord injury.

Applicant's rebuttal arguments filed February 27, 2004 averring the cited prior art's failure to provide the motivation to combine compounds of Balasubramanian and 4-aminopyridine to treat spinal cord injury have been considered, but are not found persuasive. The motivation is based on the teachings of the cited prior art that both agents are known to be useful in treating spinal cord injury. Therefore, absent evidence to the contrary, employing them concomitantly for treating the very same condition, spinal cord injuries, would be obvious (*In re Kerkhoven* 205 USPQ 1069) and additive effective would be reasonably expected.

Applicant's rebuttal arguments filed February 27, 2004 averring the cited prior art's failure to provide reasonable expectation of success have been considered, but are not found persuasive. As discussed above, concomitantly employing both

compositions, which is known to be useful in treating spinal cord injury individually, for treating the very same condition, spinal cord injuries, would be obvious (*In re Kerkhoven* 205 USPQ 1069) and additive effective would be reasonably expected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617